

Health Alert

October 19, 2001

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DIRECTOR**

SUBJECT: Hand-held Immunoassays for Detection of *Bacillus anthracis* Spores

The Department of Health and Senior Services is forwarding the following information from CDC. Please contact the Department if you have any questions at 1-800-392-0272.

October 18, 2001, 21:30 EDT (9:30 PM EDT)

Priority: Medium

Purpose: to update public and private labs and others on rapid anthrax test.

HAND-HELD IMMUNOASSAYS FOR DETECTION OF *Bacillus anthracis* SPORES

Hand-held assays (sometimes referred to as "Smart Tickets") are sold commercially for the rapid detection of *Bacillus anthracis*. These assays are intended only for the screening of environmental samples. First responder and law enforcement communities are using these as instant screening devices and should forward any positive samples to authorities for more sensitive and specialized confirmatory testing. The results of these assays should not be used to make decisions about patient management or prophylaxis. The utility and validity of these assays are unknown.

At this time, CDC does not have enough scientific data to recommend the use of these assays. The analytical sensitivity of these assays is limited by the technology, and data provided by manufacturers indicate that a minimum of 10,000 spores is required to generate a positive signal. This number of spores would suggest a heavy contamination of the area (sample). Therefore a negative result does not rule out a lower level of contamination. Data collected from field use also indicate specificity problems with some of these assays. Some positive results have been obtained with spores of the non-anthrax *Bacillus* bacteria that may be found in the environment.

For these reasons, CDC has been asked to evaluate the sensitivity and specificity of the commercially available rapid, hand-held assays for *B. anthracis*. When this study is completed, results will be made available. Conclusions from this study are not expected in the near future.

How to contact us:

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